IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

PAR PHARMACEUTICAL, INC. and ENDO PAR INNOVATION COMPANY, LLC, *Plaintiffs,* v. ALKEM LABORATORIES LTD., *Defendant*.	§ § § § § § § § § § §	Civil Action No.: 2:23-cv-00400-JRG-RSP (LEAD CASE)
v. MANKIND PHARMA LIMITED, *Defendant.*	§ § § § §	Civil Action No.: 2:23-cv-00399-JRG-RSP (MEMBER CASE)

DEFENDANT MANKIND PHARMA LIMITED'S ANSWER TO PLAINTIFFS' FIRST AMENDED COMPLAINT

Defendant Mankind Pharma Limited ("Mankind"), by and through the undersigned attorneys, submits its answer and affirmative defenses to the First Amended Complaint of Plaintiffs Par Pharmaceutical, Inc. and Endo Par Innovation Company, LLC (collectively, "Plaintiffs") as follows. Mankind denies all allegations in Plaintiffs' First Amended Complaint except those specifically admitted below. Further, Mankind denies any and all allegations, argument, and legal conclusions in the unnumbered preamble to the First Amended Complaint. This pleading is based upon Mankind's knowledge of its own activities, and upon information and belief as to the activities of others.

PARTIES

1. Plaintiff Par Pharmaceutical, Inc. ("Par Pharmaceutical") is a corporation organized and existing under the laws of the State of New York, having a principal place of

business at 300 Tice Blvd, Suite 230, Woodcliff Lake, New Jersey 07677. Par Pharmaceutical develops, manufactures, and markets pharmaceutical products in the United States, including in this judicial district.

ANSWER: Upon information and belief, Mankind admits that Par Pharmaceutical is a corporation organized and existing under the last of the State of New York and that Par Pharmaceutical has an office at 300 Tice Blvd., Suite 230, Woodcliff Lake, New Jersey 07677. Mankind admits that Par Pharmaceutical manufactures and markets pharmaceutical products in the United States. Mankind denies the remaining allegations in this paragraph.

2. Plaintiff Endo Par Innovation Company ("EPIC") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 300 Tice Blvd, Suite 230, Woodcliff Lake, New Jersey 07677.

ANSWER: Upon information and belief, Mankind admits that Endo Par Innovation Company is a limited liability company organized and existing under the laws of Delaware and that it has an office at 300 Tice Blvd, Suite 230, Woodcliff Lake, New Jersey 07677. Mankind denies the remaining allegations in this paragraph.

3. Upon information and belief, defendant Mankind is a corporation organized and existing under the laws of India, with a principal place of business at 208 Okhla Industrial Estate, Phase III, New Delhi, India 110020. Mankind manufactures, markets, distributes, and sells generic versions of branded pharmaceutical products developed and/or manufactured by Mankind for importation and sale throughout the United States, including in this judicial district.

ANSWER: Mankind admits that it is a corporation organized and existing under the laws of India, with a principal place of business at 208 Okhla Industrial Estate, Phase III, New Delhi, India 110020. Mankind admits that it develops, manufactures, and markets pharmaceutical products. Mankind further admits that pharmaceutical products that it manufactures may be imported or sold in the United States. Mankind denies the remaining allegations in this paragraph.

NATURE OF ACTION

4. This is an action for infringement of the patents in suit, based upon the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*. A copy of the '524 patent is attached hereto as Ex. 1. A copy of the '587 patent is attached hereto as Ex. 21.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent any response is necessary, Mankind admits that Plaintiffs purport to bring this action under the Patent Laws of the United States, Title 35 United States Code for infringement of the asserted patent. Mankind admits that Exhibit 1 to the First Amended Complaint purports to be a copy of the '524 patent. Mankind admits that Exhibit 21 to the First Amended Complaint purports to be a copy of the '587 patent. Mankind denies the remaining allegations in this paragraph.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) (patent infringement).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent any response is necessary, Mankind does not contest that, for purposes of this action only, the Court has jurisdiction over the subject matter of this action. Mankind denies the remaining allegations in this paragraph.

6. This Court has personal jurisdiction over Mankind because, *inter alia*, it has filed an Abbreviated New Drug Applications ("ANDA") seeking approval from the United States Food and Drug Administration ("FDA") to market and sell its generic versions of branded pharmaceutical products, including proposed generic varenicline tartrate tablets, in the United States, and FDA-approved products manufactured by Mankind are marketed and sold throughout the United States, including in this district. Moreover, the FDA recently approved Mankind's ANDA for generic varenicline tartrate tablets, and upon information and belief, Mankind intends to manufacture, market, distribute, and sell those tablets for importation and sale throughout the United States, including in the State of Texas and in this district. Accordingly, Mankind has and will purposefully avail itself of the privilege of doing business in the State of Texas and this district, directly or indirectly through its subsidiaries or agents, including through the importation, marketing, distribution, and sale of its generic varenicline tartrate products in the State of Texas and in this district.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent any response is necessary, Mankind does not contest personal jurisdiction

for purposes of this case only. Mankind reserves the right to contest jurisdiction or venue in any other case. Mankind denies the remaining allegations in this paragraph.

7. In the alternative, this Court may also exercise jurisdiction over Mankind pursuant to Fed. R. Civ. P. 4(k)(2) to the extent that Mankind, as a foreign defendant, is not subject to personal jurisdiction in any state's court of general jurisdiction, based on Mankind's contacts with the United States as a whole, including without limitation through the importation, distribution, and sales of its pharmaceutical products throughout the United States, including in this district.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent any response is necessary, Mankind does not contest personal jurisdiction for purposes of this case only. Mankind reserves the right to contest jurisdiction or venue in any other case. Mankind denies the remaining allegations in this paragraph.

8. Venue as to Mankind is proper in this district pursuant to 28 U.S.C. §§ 1391(c), and 1400(b) because, *inter alia*, Mankind is a foreign corporation and as such may be sued in any judicial district in the United States in which Mankind is subject to the court's personal jurisdiction.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent any response is necessary, Mankind does not contest that venue is proper for purposes of this case only, although venue is clearly more convenient in the District of Delaware and this case should be transferred to that venue pursuant to 28 U.S.C. § 1404(a). Mankind reserves the right to contest venue in any other case. Mankind denies the remaining allegations in this paragraph.

THE DRUG APPROVAL PROCESS

9. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the FDA, typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a). They must submit to FDA information on all patents covering the new drug or a method of using that drug, and FDA then lists the patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1) and (c)(2).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent any response is necessary, Mankind admits that a company must obtain approval to introduce or deliver for introduction into interstate commerce any new drug pursuant to 21 U.S.C. § 355(a). Mankind further admits that an applicant must submit the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug and that claims the drug or a method of using such drug. *See* 21 U.S.C. § 355(b)(1). Mankind further admits that the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) identifies drug products approved by the FDA and related patent and exclusivity information. Mankind denies the remaining allegations in this paragraph.

10. A company seeking to market a generic version of a previously approved drug may file an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. §355(j). This "abbreviated" process allows the generic manufacturer to piggyback on the first company's data and FDA's prior finding of safety and efficacy by demonstrating, among other things, bioequivalence to the previously approved drug (the "listed drug" or "branded drug").

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent any response is necessary, Mankind admits that a company may file an abbreviated new drug application ("ANDA") for the approval of a new drug pursuant to 21 U.S.C. § 355(j). Mankind admits that an ANDA must contain, among other things, information to show that the proposed new drug is bioequivalent to a previously approved drug ("listed drug"). Mankind denies the remaining allegations in this paragraph.

11. To protect innovation and prevent improper entry into the market by infringing drugs, Congress has put in place a process for resolving patent disputes relating to generic drugs, pursuant to which an ANDA filer must provide certifications, such as certifying its generic drug will not infringe or the patent is invalid (which is known as a "Paragraph IV Certification"), as to each of the patents listed in the Orange Book for the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). Upon submitting a Paragraph IV Certification, an ANDA filer must provide notice to the NDA holder and patent owner (a "Paragraph IV Notice"),

along with a detailed statement of the factual and legal bases for the applicant's belief that the challenged patent is invalid or not infringed by the proposed generic product. 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95. Frequently, the ANDA filer will also provide confidential access to the portions of the ANDA relevant to evaluating infringement. *See* 21 U.S.C. § 355(c)(3)(D)(i)(III); 21 C.F.R. § 314.52(c)(7).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent any response is necessary, Mankind admits an ANDA must contain, among other things, a certification that, in the opinion of the applicant and to the best of its knowledge, with respect to each patent which claims the listed drug: that such patent information has not been filed; that such patent has expired; of the date on which such patent will expire; or that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii). Mankind further admits that if the ANDA contains a certification that a patent is invalid or not infringed, the applicant must provide notice that the patent is invalid or will not be infringed, which notice includes a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(B). Mankind lacks knowledge or sufficient information to form a belief about the truth of the allegations regarding what an "ANDA filer" will "frequently" do and therefore denies them. Mankind denies the remaining allegations in this paragraph.

12. If the patentee or NDA holder files a patent infringement action within 45 days of receiving a Paragraph IV Notice, final approval of the generic drug is subject to a 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3). The 30-month stay is important because it protects innovators from generic manufacturers seeking to copy the innovation and launch their generic products into the market, causing severe and irreversible financial harm that is nearly impossible to fully quantify, before the innovator has an opportunity to vindicate its patent rights. Put another way, the innovator company is assured of a 30-month period during which it may try to enforce its intellectual property rights and resolve any patent dispute before the generic product enters the market. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent any response is necessary, Mankind admits that pursuant to 21 US.C. § 355(j)(5)(B)(iii), if the ANDA filer made a Paragraph IV certification and before the expiration of

45 days after the date on which notice of the Paragraph IV certification is received an action is brought for infringement of the patent that is the subject of the certification, the FDA's approval of the ANDA shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the Paragraph IV notice. Mankind denies the remaining allegations in this paragraph.

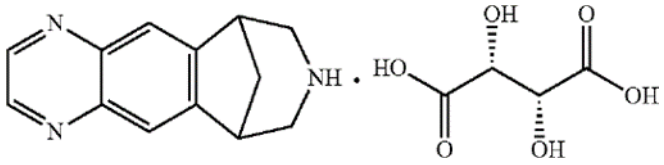
13. Although these statutory provisions do not strictly apply here, the underlying principles do. The original branded product, Pfizer's CHANTIX® tablets, was pulled from the market because of unacceptably high levels of potentially carcinogenic impurities. Endo innovated and reduced the levels of impurities, obtained FDA approval, and then became the de facto brand. The Hatch-Waxman Act statutory regime reflects Congress' intent that patent disputes regarding generic drug products be resolved before the generic manufacturer causes irreparable harm by prematurely launching its infringing products into the marketplace, and that is what Par seeks here.

ANSWER: Mankind admits that the statutory provisions cited and referenced in paragraphs 10 through 13 do not apply here. Mankind denies the remaining allegations in this paragraph.

FACTUAL BACKGROUND

Nitrosamine Impurities in Varenicline Tartrate Products

14. Varenicline tartrate is a synthetic drug useful in treating nicotine dependency, addiction, and withdrawal. It has the following chemical formula:



ANSWER: Mankind admits that varenicline tartrate is a synthetic drug that is used to treat nicotine dependency, addiction, and withdrawal. Mankind further admits that the above image depicts the chemical structure of varenicline tartrate. Mankind denies the remaining allegations in this paragraph.

15. In 2006, the FDA authorized Pfizer to make and sell varenicline tartrate tablets under the trade name CHANTIX® as a partial agonist selective for certain subtypes of nicotinic

receptors and indicated for smoking cessation. At its height, Pfizer's revenues from its sales of CHANTIX® were in excess of $1 billion per year.

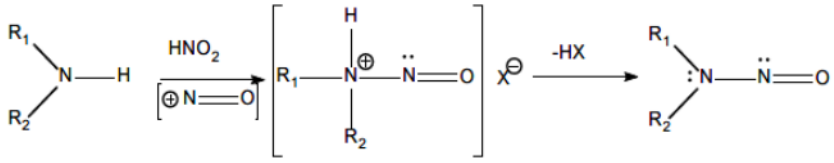
ANSWER: Mankind admits that the FDA's website Drugs@FDA lists an "Action Date" of May 10, 2006, for the "Action Type" of "Approval" for the "Drug Name" CHANTIX. Mankind admits that the FDA's approval letter is addressed to Pfizer Inc. Mankind lacks knowledge or sufficient information to form a belief about the truth of the allegations regarding Pfizer's revenues from the sales of CHANTIX® and therefore denies them. Mankind denies the remaining allegations in this paragraph.

16. However, due to the presence of unacceptably high levels of a nitrosamine impurity (N-nitroso-varenicline) associated with potential increased cancer risk in humans, Pfizer withdrew CHANTIX® from the market in or about July 2021.

ANSWER: Upon information and belief, Mankind admits that Pfizer withdrew CHANTIX® from the market. Mankind lacks knowledge or sufficient information to form a belief about the truth of the remaining allegations in this paragraph and therefore denies them.

17. As described in FDA guidance concerning the control of nitrosamine impurities in pharmaceutical drug products, nitrosamines are a class of compounds with a chemical structure in which a nitroso group is bonded to an amine (R1N(-R2)-N=O), which can form by a nitrosating reaction between amines and nitrous acid, as shown in the following figure:

Figure 1. Representative Reaction to Form Nitrosamines



See Ex. 2 ("Control of Nitrosamine Impurities in Human Drugs", Guidance for Industry, U.S. Food and Drug Administration Center for Drug Evaluation and Research (Feb. 2021, Rev. 1)), at 3-4 and Figure 1.

ANSWER: Mankind admits that Exhibit 2 to the Complaint, titled "Control of Nitrosamine Impurities in Human Drugs, Guidance for Industry" was published by the FDA and

states that "[t]he term *nitrosamine* describes a class of compounds having the chemical structure of a nitroso group bonded to an amine (R1N(-R2)-N=O), as shown in Figure 1. The compounds can form by a nitrosating reaction between amines (secondary, tertiary, or quaternary amines) and nitrous acid (nitrite salts under acidic conditions)." Mankind further admits that Figure 1 above appears in Exhibit 2. Mankind denies the remaining allegations in this paragraph.

18. The unexpected discovery in 2018 and 2019 of the presence of nitrosamines in several pharmaceutical drug products led the FDA and other international regulators to conduct a detailed analysis of these impurities in affected active pharmaceutical ingredients ("API") and drug products and the potential root causes of their presence in those products. Based on that analysis, in September 2020, the FDA issued guidance to pharmaceutical manufacturers, including recommendations for evaluating the risk for nitrosamine contamination or formation in their APIs and drug products and the establishment of acceptable daily intake limits for particular nitrosamine impurities found in drug products. The FDA updated that guidance in February 2021. *See* Ex. 2.

ANSWER: Mankind admits that Exhibit 2 to the Complaint, titled "Control of Nitrosamine Impurities in Human Drugs, Guidance for Industry" was published by the FDA, is dated February 2021, and states that "[t]his document revises the guidance of the same title issued in September 2020." Mankind further admits that Exhibit 2 states, among other things, that "FDA recommends the following acceptable intake (AI) limits for the nitrosamine impurities NDMA, NDEA, NMBA, NMPA, NIPEA, and NDIPA (Table 1)." Mankind further admits that Table 1 in Exhibit 2 lists "AI Limits for NDMA, NDEA, NMBA, NMPA, NIPEA, and NDIPA in Drug Products." Mankind lacks knowledge or sufficient information to form a belief about the truth of the remaining allegations in this paragraph and therefore denies them.

19. In connection with that evaluation and guidance, in September 2020, the FDA established an acceptable daily intake limit (AI) of varenicline nitrosamine impurities of 37 nanograms, which equates to 18.5 parts per million ("ppm") of those impurities per 1 mg of varenicline API for CHANTIX® and other FDA-approved varenicline tartrate smoking cessation products.

ANSWER: Mankind lacks knowledge or sufficient information to form a belief about the truth of the allegations in this paragraph and therefore denies them.

20. On July 2, 2021, the FDA announced that Pfizer had discovered the presence of N-nitroso-varenicline at levels above the FDA's acceptable intake limit in nine commercial lots of CHANTIX® and that, as a result, Pfizer was recalling those lots from warehouses. Pfizer subsequently expanded that recall and discontinued sales of CHANTIX®. *See, e.g.,* https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix; Fed. Reg., Vol. 88, No. 38 at 12384-85.

ANSWER: Mankind admits that https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix#:~:text=Update%20%5B9%2F17%2F2021,N%2Dnitroso%2Dvarenicline%20levels. states, "[7/02/2021] FDA is alerting patients and health care professionals to Pfizer's voluntary recall of nine lots of the smoking cessation drug, varenicline (brand name Chantix), to the warehouse level. The company is recalling varenicline because it may contain levels of a nitrosamine impurity, called N-nitroso-varenicline, above FDA's acceptable intake limit." Mankind further admits that Fed. Reg., Vol. 88, No. 38 at 12384-85 states "PF Prism CV has voluntarily discontinued marketing of CHANTIX (varenicline tartrate) tablets, 0.5 mg and 1 mg." Mankind lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore denies them.

21. Despite how successful sales of CHANTIX® were, Pfizer has been unable in the two years since it pulled CHANTIX® from the market to reformulate its varenicline tartrate tablets so as to reduce the nitrosamine impurities in them to a level that meets the FDA-mandated acceptable daily intake limits. Accordingly, Pfizer no longer sells any varenicline tartrate products.

ANSWER: Mankind lacks knowledge or sufficient information to form a belief about the truth of the allegations in this paragraph and therefore denies them.

22. In February 2023, the FDA announced that it would not approve any future abbreviated new drug applications ("ANDAs") for varenicline tartrate drug products that do not meet the applicable acceptable daily intake limits for nitrosamine impurities. *See* Fed. Reg., Vol. 88, No. 38 at 12384-85.

ANSWER: Mankind admits that Fed. Reg., Vol. 88, No. 38, at 12385 states "Additional ANDAs for this drug product may be approved by the Agency as long as they meet all other legal

and regulatory requirements for the approval of ANDAs, including satisfying any applicable acceptable intake limit for nitrosamine impurities." Mankind lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore denies them.

Par's Varenicline Tartrate Products

23. Par was a first filer of an ANDA (ANDA No. 2011785) for varenicline tartrate products, seeking FDA approval to generic varenicline tartrate tablets in 0.5 mg and 1 mg dosage strengths.

ANSWER: Mankind admits that Drugs@FDA: FDA-Approved Drugs lists "PAR PHARM INC" as the Company, "VARENICLINE TARTRATE" as the Active Ingredient, "TABLET" as the Dosage Form, and "EQ 0.5MG BASE" and "EQ 1MG BASE" as the Strengths in connection with ANDA No. 201785. Mankind denies the remaining allegations in this paragraph.

24. When Par scientists began working on Par's varenicline tartrate tablets, there was no published literature about the presence of nitrosamine impurities in varenicline products, let alone public information about the specific chemical structure of any such impurities or about how to detect them. Accordingly, the Par scientists were effectively starting from scratch in terms of seeking to identify and control the extent of varenicline-related nitrosamine impurities that might be found in Par's varenicline API.

ANSWER: Mankind lacks knowledge or sufficient information to form a belief about the truth of the allegations in this paragraph and therefore denies them.

25. Par engaged in extensive work to develop analytical methods to identify, detect, and quantify the nitrosamine impurities in its varenicline API, as well as a commercially practicable method for reducing those impurities to acceptable levels.

ANSWER: Mankind lacks knowledge or sufficient information to form a belief about the truth of the allegations in this paragraph and therefore denies them.

26. In contrast to Pfizer's CHANTIX® products, Par successfully developed varenicline tablets that have remarkably low levels of nitrosamine impurities—less than 5 ppm per 1 mg of varenicline API, *i.e.*, well below the FDA's acceptable daily intake limit of 18.5 ppm.

ANSWER: Mankind lacks knowledge or sufficient information to form a belief about the truth of the allegations in this paragraph and therefore denies them.

27. Accordingly, on August 11, 2021, the FDA approved Par's ANDA, which resulted in the availability of the first FDA approved varenicline tartrate tablets with nitrosamine levels that satisfied the FDA's acceptable intake limit for nitrosamine impurities.

ANSWER: Mankind admits that the FDA's website, https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/2021-first-generic-drug-approvals, lists August 11, 2021, as the "ANDA Approval Date" for Par's ANDA No. 201785. Mankind lacks knowledge or sufficient information to form a belief about the truth of the remaining allegations in this paragraph and therefore denies them.

28. Indeed, in February 2022, the FDA posted the results of testing it had conducted on several other varenicline tartrate tablets, and those results showed that Par's varenicline tablets have dramatically lower nitrosamine levels than any of the other commercially available products:

Company (Manufacturer)	Product	Lots Tested	N-nitroso-varenicline level in micrograms/tablet (nanograms/tablet)	N-nitroso-varenicline level in parts per million (ppm)
Pfizer	Chantix (varenicline) 1mg	EA6080, EC9841, EC9847, EC9848, EX2099, DR5086	0.15-0.47 (150-470)	155-474
Par Pharmaceuticals	Varenicline 1 mg	31960807, 31960801	0.003 (3)	3
Apotex	APO-Varenicline Tartrate 1 mg)	TG2183, TG2181, TG2182	0.027-0.044 (27-44)	27-44
Apotex	APO-Varenicline Tartrate 0.5 mg	TG2180, TG2178, TG2179	0.014-0.021 (14-21)	27-42

See Ex. 3 ("Laboratory analysis of varenicline products", FDA Feb. 8, 2022).

ANSWER: Mankind admits that Exhibit 3 to the Complaint includes the table above in paragraph 29. Mankind further admits that the FDA posted its laboratory analysis of varenicline products. Mankind lacks knowledge or sufficient information to form a belief about the truth of the allegations in this paragraph and therefore denies them.

29. Because the nitrosamine levels in those other tablets exceeded the FDA's acceptable daily intake levels, each of them had to be withdrawn from the market. The FDA granted Apotex Corp. a limited waiver to sell varenicline tablets to ensure adequate supply to the U.S. market, but that waiver expired as of at least May 2022.

ANSWER: Mankind lacks knowledge or sufficient information to form a belief about the truth of the allegations in this paragraph and therefore denies them.

30. Making varenicline tartrate tablets with the low levels of nitrosamine required by the FDA is difficult to do, as evidenced by the fact that Pfizer has been unable to reformulate its CHANTIX® product to meet those requirements despite the huge incentive it has had to do so (*i.e.*, the loss of a product that had $1 billion in annual revenues).

ANSWER: Mankind lacks knowledge or sufficient information to form a belief about the truth of the allegations in this paragraph and therefore denies them.

Par's Patented Technology

31. As the first pharmaceutical manufacturer able to overcome the difficulties associated with developing FDA-approvable varenicline tartrate tablets with nitrosamine impurities below the FDA's acceptable daily intake level—which other manufacturers like Pfizer have been unable to do, Par filed patent applications directed to its novel technologies for manufacturing varenicline tartrate tablets with low levels of nitrosamine impurities, including U.S. Patent Application No. 17/930,824 (the "'824 application").

ANSWER: Mankind admits that U.S. Patent Application No. 17/930,824 lists Par Pharmaceutical, Inc. as the applicant. Mankind denies the remaining allegations in this paragraph.

32. On June 7, 2023, the United States Patent and Trademark Office ("PTO") issued a Notice of Allowance and Fee(s) Due, stating that the then-pending patent claims of the '824 application would be allowed for patenting.

ANSWER: Mankind admits that on June 7, 2023, the United States Patent and Trademark Office ("PTO") issued a Notice of Allowance and Fee(s) Due for the '824 application. Mankind denies the remaining allegations in this paragraph.

33. Thereafter, on August 8, 2023, the PTO issued the '524 patent, titled "Varenicline Compound and Process of Manufacture Thereof." Representative claim 1 of the '524 patent recites the following:

1. A method of making a varenicline tartrate tablet comprising less than 50 ppm of nitrosamine impurities, the method comprising:
(a) mixing varenicline free base with tartaric acid to form varenicline tartrate
(b) means for reducing the nitrosamine impurities to less than 50 ppm per tablet as measured by LC-ESI-HRMS Method;
wherein the means comprises an acid-base treatment.
Ex. 1, claim 1.

ANSWER: Mankind admits that the '524 patent is titled "Varenicline Compound and Process of Manufacture Thereof" and that the Date of Patent is August 8, 2023. Mankind admits that claim 1 of the '524 patent reads:

1. A method of making a varenicline tartrate tablet comprising less than 50 ppm of nitrosamine impurities, the method comprising:

(a) mixing varenicline free base with tartaric acid to form varenicline tartrate

(b) means for reducing the nitrosamine impurities to less than 50 ppm per tablet as measured by LC-ESI-HRMS Method;

wherein the means comprises an acid-base treatment.

Mankind denies the remaining allegations in this paragraph.

34. Earlier, on March 14, 2023, the PTO had issued to Par U.S. Patent No. 11,602,537 (the "'537 patent"). The claims of the '537 patent are directed to Par's novel pharmaceutical varenicline tartrate tablet compositions.

ANSWER: Mankind admits that U.S Patent No. 11,602,537 lists March 14, 2023, as the Date of Patent and that Par Pharmaceutical, Inc. is listed as the Assignee on the face of the patent. Mankind denies the remaining allegations in this paragraph.

35. On October 10, 2023, the PTO issued the '587 patent, titled "Varenicline Compound and Process of Manufacture Thereof." Representative claim 1 of the '587 patent recites the following:

> 1. A pharmaceutical composition in the form of a tablet, comprising varenicline tartrate, wherein the tablet comprises less than 50 ppm of N-nitroso-varenicline (7,8,9,10-tetrahydro-8-nitroso-6,10-Methano-6H-pyrazino [2,3-h][3] benzazepine) impurity as measured by LC-ESI-HRMS (U.S. FDA Method) and less than 0.15% (w/w) of diamide (Bis (7,8,9,10-tetrahydro-6,10-methano-6H- pyrazino[2,3-h][3]-benzazepine)-amide) impurity as measured by RS Method-II.

Ex. 21, claim 1.

ANSWER: Mankind admits that the '587 patent is titled "Varenicline Compound and Process of Manufacture Thereof" and that the Date of Patent is October 10, 2023. Mankind admits that claim 1 of the '587 patent reads:

> 1. A pharmaceutical composition in the form of a tablet, comprising varenicline tartrate, wherein the tablet comprises less than 50 ppm of N-nitroso-varenicline (7,8,9,10-tetrahydro-8-nitroso-6,10-Methano-6H-pyrazino [2,3-h][3] benzazepine) impurity as measured by LC-ESI-HRMS (U.S. FDA Method) and less than 0.15% (w/w) of diamide (Bis (7,8,9,10-tetrahydro-6,10-methano-6H- pyrazino[2,3-h][3]-benzazepine)-amide) impurity as measured by RS Method-II.

Mankind denies the remaining allegations in this paragraph.

36. Par Pharmaceuticals is the assignee and owner of the patents in suit, and EPIC is an exclusive licensee of those patents.

ANSWER: Mankind admits that the '524 patent and the '587 patent list Par Pharmaceutical, Inc. as the Assignee on the face of the patents. Mankind lacks knowledge or sufficient information to form a belief about the truth of the allegations in this paragraph and therefore denies them.

Mankind's Infringement of the Patents in Suit

37. Mankind submitted an ANDA (ANDA No. 217151, the "Mankind ANDA") pursuant to 35 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture and sale of generic varenicline tartrate tablets in the same 0.5 mg and 1 mg dosage strengths as sold by Par (the "Accused Tablets"). The Mankind ANDA was approved by the FDA on August 1, 2023.

ANSWER: Mankind denies that Mankind submitted ANDA No. 217151 to the FDA. Mankind admits that ANDA No. 214255 was submitted on behalf of Mankind to the FDA pursuant to 35 U.S.C. § 355(j), seeking FDA approval to engage in the manufacture or sale of varenicline tartrate tablets, 0.5 mg and 1 mg. Mankind admits that ANDA No. 214255 was approved by the FDA on August 1, 2023. Mankind denies the remaining allegations in this paragraph.

38. Par became aware of the Mankind ANDA shortly thereafter (ANDAs are maintained as confidential by the FDA and not publicly disclosed), and on August 4, 2023, Par wrote Mankind a notice letter advising Mankind of Par's patented technologies, including those embodied in Par's '537 patent and soon-to-be issued '524 patent ("First Notice Letter"). A copy of the First Notice Letter is attached as Ex. 4.

ANSWER: Mankind admits that what purports to be a copy of Par's August 4, 2023 correspondence is attached as Exhibit 4 to the Complaint. Mankind further admits that Par's August 4, 2023 correspondence states, among other things, "We write on behalf of Par Pharmaceuticals Inc. ('Par') to advise Mankind Pharma Limited ('Mankind Pharma') that the U.S. Patent and Trademark Office ('PTO') has granted Par certain patent rights regarding varenicline pharmaceutical compositions. In particular, the PTO has issued U.S. Patent No. 11,602,537 (''537 patent') and has allowed additional patent claims in a divisional application which will issue as U.S. Patent No. 11,717,524 (the ''524 Patent') on August 8, 2023." Mankind denies the remaining allegations in this paragraph.

39. Among other things, the First Notice Letter advised Mankind that Par had learned of the FDA's approval of its ANDA and believed it was highly likely that the Accused Tablets would infringe, *inter alia*, the allowed claims of the forthcoming '524 patent because:

- FDA's "Drugs@FDA" website confirms that the active pharmaceutical ingredient ("API") in Mankind's tablets is varenicline tartrate. Ex. 5 (Drugs@FDA Website).
- The Accused Tablets will contain less than 50 ppm of nitrosamine impurities, as claimed, because the FDA's acceptable intake limit for the claimed nitrosamine impurities is only 37 ng per day, which translates to 18.5 ppm. *See, e.g.,* https://www.fda.gov/drugs/drug- safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline- chantix.
- The only commercially-viable methods for making varenicline tartrate tablets with the claimed low levels of nitrosamine impurities that Par is aware of are the methods taught and claimed in the '824 application, such that Par believes it is highly likely that Mankind is using those methods (or an equivalent thereof) to make the Accused Tablets.

See Ex. 4.

ANSWER: Mankind admits that Par's August 4, 2023 correspondence states, among other things, "We understand that the FDA approved Mankind Pharma's ANDA No. 214255 for varenicline tartrate tablets on August 1, 2023. As just noted, Par believes it is highly likely that Mankind Pharma's varenicline products infringe upon Par's patents, including for example claim 1 of the forthcoming '524 patent. The basis for Par's belief in that regard is that, among other things, the FDA's 'Drugs@FDA' website confirms that the active pharmaceutical ingredient ('API') in Mankind Pharma's tablets is varenicline tartrate, as claimed; the FDA's acceptable intake limit for the claimed nitrosamine impurities is 37 ng per day, which translates to 18.5 ppm, such that Mankind Pharma's approved tablets must have nitrosamine impurity levels within the claimed ranges; and the only commercially-viable methods for making varenicline tartrate tablets

with the claimed low levels of nitrosamine impurities that Par is aware of are the methods taught and claimed in its patents, such that Par believes it is highly likely that Mankind Pharma is using those methods (or an equivalent thereof) to make its tablets." Mankind further admits that what purports to be a page from the FDA's "Drugs@FDA" website is attached as Exhibit 5 to the Complaint. Mankind denies the remaining allegations in this paragraph.

40. Moreover, Par asked Mankind to agree to provide its outside counsel with confidential access to the relevant portions of Mankind's ANDA, consistent with standard practice in more typical Hatch-Waxman Act ANDA patent litigations, in order to enable Par to investigate and confirm its beliefs as to Mankind's likely infringement. Par also requested that Mankind notify Par if it denied that the sale of the Accused Patents would infringe the '524 patent and the basis for any such belief.

ANSWER: Mankind admits that Par's August 4, 2023 correspondence states, among other things, "we ask that Mankind Pharma to provide us with confidential access to the CMC sections of its ANDA and the DMF for its API, on terms similar to those that are typically provided in Offers of Confidential Access to ANDAs pursuant to 21 U.S.C. § 355(c)(3)(D)(i)(III) and 21 C.F.R. § 314.52(c)(7) ('OCAs')." Mankind further admits that Par's August 4, 2023 correspondence states that "this matter is not subject to those provisions." Mankind denies that this action is a "Hatch-Waxman ANDA patent litigation[]." Mankind denies the remaining allegations in this paragraph.

41. Mankind ignored the First Notice Letter.

ANSWER: Mankind denies the allegations in this paragraph.

42. Then, on August 11, 2023, Par wrote Mankind a second notice letter, advising Mankind that the PTO had just issued the '524 patent and enclosing a copy of the patent ("Second Notice Letter"). A copy of the Second Notice Letter is attached as Ex. 6.

ANSWER: Mankind admits that what purports to be a copy of Par's August 11, 2023 correspondence is attached as Exhibit 6 to the Complaint. Mankind further admits that Par's August 11, 2023 correspondence state, among other things, "Please be advised that, on August 8,

2023, the U.S. Patent and Trademark Office ('PTO') issued U.S. Patent No. 11,717,524 (the ''524 Patent'). … A copy of the '524 patent is enclosed for your convenience." Mankind denies the remaining allegations in this paragraph.

43. Among other things, the Second Notice Letter reiterated Par's belief that it was highly likely that the commercial sale of Mankind's approved varenicline tartrate tablets would infringe at least claim 1 of the '524 patent, as well as Par's requests for confidential access to the relevant portions of Mankind's ANDA and that Mankind notify Par if it believed that its tablets would not infringe Par's patent rights, including the basis for any such belief.

ANSWER: Mankind admits that Par's August 11, 2023 correspondence states, among other things, "Par believes it is highly likely that any commercial sales of the subject of Mankind Pharma's ANDA No. 217151 for varenicline tartrate tablets would infringe the claims of the '524 Patent, including at least under 35 U.S.C. §§ 271(a), (b), and/or (g). … Please let us know whether, and on what basis, Mankind Pharma denies that the sales of its approved varenicline tablets would infringe the claims of the '524 patent. Par reiterates its request to Mankind Pharma to provide Par with confidential access to the CMC sections of its ANDA and the DMF for its API, on terms similar to those that are typically provided in Offers of Confidential Access to ANDAs pursuant to 21 U.S.C. § 355(c)(3)(D)(i)(III) and 21 C.F.R. § 314.52(c)(7) ('OCAs')." Mankind denies the remaining allegations in this paragraph.

44. The Second Notice Letter further advised Mankind that if Par sued to enforce the '524 patent, Par intended to seek to impose on Mankind the burden of establishing that its tablets are not made in accordance with Par's patented manufacturing process pursuant to 35 U.S.C. § 295.

ANSWER: Mankind admits that Par's August 11, 2023 correspondence states, among other things, "Please note that Par intends to enforce its patent rights as appropriate and warranted under the circumstances. Please further note that in any lawsuit brought by Par to enforce the method of manufacture claims of the '524 Patent, Mankind Pharma would have the burden, pursuant to 35 U.S.C. § 295, of establishing that its products are not made in accordance with Par's

patented process." Mankind denies that 35 U.S.C. § 295 is applicable and denies that Mankind has the burden of establishing noninfringement. Mankind denies the remaining allegations in this paragraph.

45. On August 14, 2023, Mankind finally responded to Par's notice letter. Mankind provided cursory allegations of non-infringement, without any details or specifics, and offered to "engage in a discussion" about providing confidential access to its ANDA. A copy of that letter is attached as Ex. 7. Since that time, Mankind has unreasonably stalled such discussions and, despite Par's diligent efforts, has yet to produce to Par any information about either the composition of its tablets or the methods used to manufacture them.

ANSWER: Mankind admits that a copy of Mankind's August 14, 2023 correspondence is attached as Exhibit 7 to the Complaint. Mankind further admits that Mankind's August 14, 2023 correspondence states, among other things, "we disagree with your assertions that you have a reasonable basis for accusing Mankind of infringing the '537 and '524 patents. As you admit, you do not possess information regarding the manufacturing process for the Mankind ANDA product and therefore have no legitimate reason to believe that the process or product would infringe those patents. Your suggestion that there is no other way to make the product having accepting impurity levels is simply false." Mankind denies the remaining allegations in this paragraph.

46. In particular, on August 15, 2023, Par responded to Mankind's letter (the "Third Notice Letter") by reiterating its request that Mankind identify the basis for any belief that it is not utilizing Par's patented manufacturing methods and that if Mankind refused to disclose those methods, then in any lawsuit enforcing Par's patent rights, Mankind would likely have the burden of establishing that it is not using those methods to make the Accused Tablets. A copy of the Third Notice Letter is attached as Ex. 8. Mankind has not provided the requested information and has unreasonably stalled reaching agreement on the terms of a non-disclosure agreement. *See* copies of the parties' subsequent correspondence, attached as Exs. 9 through 13.

ANSWER: Mankind admits that what purports to be a copy of Par's August 15, 2023 correspondence is attached as Exhibit 8 to the Complaint. Mankind admits that Par's August 15, 2023 correspondence states, among other things, "We have no interest in pursuing claims against non-infringing tablets, but because manufacturing is occurring outside the US, if we cannot

determine the process Mankind is using after reasonable efforts, the burden of establishing non-infringement would fall on Mankind under 35 U.S.C. § 295." Mankind denies that 35 U.S.C. § 295 is applicable and denies that Mankind has the burden of establishing noninfringement. Mankind further admits that what purport to be copies of additional email correspondence between Par and Mankind are attached as Exhibits 9 through 13 to the Complaint. Mankind denies the remaining allegations in this paragraph.

47. Despite receiving notice of the '537 and '524 Patents, Mankind launched the Accused Tablets in the United States, and is importing them into and selling them in the United States, with willful disregard for Par's patent rights.

ANSWER: Mankind admits that the products that are the subject of ANDA No. 214255 are currently offered for sale in the United States. Mankind denies the remaining allegations in this paragraph.

48. Par has been unable to fully ascertain the processes that Mankind uses to manufacture its varenicline API and the Accused Tablets, or have them made, despite having made diligent and reasonable efforts to do so. In particular, and among other things:

A. Detailed information about those manufacturing processes is contained in the Mankind ANDA and/or the accompanying Drug Master File ("DMF") for the varenicline API contained in the Accused Tablets, both of which would have been submitted to the FDA and are maintained by the FDA on a confidential basis. Mankind refused to provide copies of them to Par's counsel on a confidential basis prior to the commencement of this suit. Par has now obtained in the course of discovery some information concerning the manufacturing processes used to make the Accused Tablets and components thereof, but Mankind has yet to produce a copy of the applicable DMF, and Par continues to pursue that and other additional information through the course of discovery.

B. Par wrote to Mankind on multiple occasions to try to ascertain any basis on which Mankind might claim that it is not using Par's patented technologies, but Mankind has yet to identify a valid basis on which to believe that it is not using those technologies to manufacture the Accused Tablets.

ANSWER: Mankind denies the allegations in this paragraph.

COUNT I
INFRINGEMENT OF THE '524 PATENT

49. Par incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Mankind incorporates each of the preceding answers as if fully set forth herein.

50. Mankind's submission of the Mankind ANDA to the FDA, which seeks approval to engage in the commercial manufacture, use, and sale of generic varenicline tartrate tablets prior to the expiration of the '524 Patent, constitutes infringement of the '524 Patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Mankind denies the allegations in this paragraph.

51. The manufacture, importation, and commercial sale of the Accused Tablets before expiration of the '524 patent constitutes infringement of the '524 patent under at least 35 U.S.C. § 271(b) and (g), including without limitation claim 1 thereof as recited above.

ANSWER: Mankind denies the allegations in this paragraph.

52. In particular, for the reasons described in the First Notice Letter, among others, Mankind is making the varenicline API used in the Accused Tablets, or having it made, in accordance with the manufacturing methods taught and claimed in the '524 patent, importing them into the United States, and selling them or having them sold throughout the United States.

ANSWER: Mankind denies that it is making or will make varenicline API in accordance with the manufacturing methods claimed in the '524 patent. Mankind admits that the products that are the subject of ANDA No. 214255 are imported into the United States. Mankind denies the remaining allegations in this paragraph.

53. As noted above, representative claim 1 of the '524 patent recites the following:

> 1. A method of making a varenicline tartrate tablet comprising less than 50 ppm of nitrosamine impurities, the method comprising:
> (a) mixing varenicline free base with tartaric acid to form varenicline tartrate
> (b) means for reducing the nitrosamine impurities to less than 50 ppm per tablet as measured by LC-ESI-HRMS Method;
> wherein the means comprises an acid-base treatment.

ANSWER: Mankind admits that claim 1 of the '524 patent reads:

> 1. A method of making a varenicline tartrate tablet comprising less than 50 ppm of nitrosamine impurities, the method comprising:
> (a) mixing varenicline free base with tartaric acid to form varenicline tartrate
> (b) means for reducing the nitrosamine impurities to less than 50 ppm per tablet as measured by LC-ESI-HRMS Method;
> wherein the means comprises an acid-base treatment.

Mankind denies the remaining allegations in this paragraph.

54. Par has used its best efforts to confirm its beliefs that Mankind is infringing that claim (among others), including the following:

A. The approved prescribing information and labeling confirms that the active pharmaceutical ingredient ("API") in Mankind's tablets is varenicline tartrate, as claimed. *See, e.g.,* Ex. 5 (Drugs@FDA Website).

B. The Accused Tablets have less than 50 ppm of nitrosamine impurities, as claimed.

C. With respect to the remaining limitations of claim 1, Par has been unable to fully ascertain the processes that Mankind uses to manufacture its varenicline API and the Accused Tablets, or have them made, despite having made diligent and reasonable efforts to do so, as summarized above. At a minimum, based on the information available to Par to date, the Accused Tablets are manufactured in accordance with the steps of at least claim 1 of the '524 patent.

ANSWER: Mankind denies the allegations in this paragraph.

55. In light of the above, upon information and belief, Par believes it is highly likely that Mankind is making or will make the Accused Tablets via the manufacturing methods taught and claimed in the '524 patent, including without limitation claim 1 thereof.

ANSWER: Mankind lacks knowledge or sufficient information to form a belief about the truth of the allegations regarding what Par "believes" and therefore denies them. Mankind denies that it is making or will make the products that are the subject of ANDA No. 214255 via the manufacturing methods claimed in the '524 patent. Mankind denies the remaining allegations in this paragraph.

56. Upon information and belief, Mankind is manufacturing the Accused Tablets in India and importing them into the United States for commercial sale throughout the country.

ANSWER: Mankind admits that Mankind manufactures the products that are the subject of ANDA No. 214255 in India. Mankind further admits that the products that are the subject of ANDA No. 214255 are imported into the United States for commercial sale. Mankind denies the remaining allegations in this paragraph.

57. With full knowledge of the '524 patent and willful disregard of Par's accompanying patent rights, Mankind has continued and is continuing make and import the Accused Tablets for sale to customers in the United States, thereby infringing the '524 patent under at least 35 U.S.C. § 271(g).

ANSWER: Mankind denies the allegations in this paragraph.

58. To the extent Mankind has not and will not itself import, use, sell, or offer to sell the Accused Products in the United States, it has and will knowingly, intentionally, and actively induce and encourage others to do so, with full knowledge of the '524 patent, and thereby infringe the '524 patent under 35 U.S.C. § 271(b).

ANSWER: Mankind denies the allegations in this paragraph.

59. Mankind's infringement, if unchecked, will cause Par to suffer significant, immediate and irreparable damage.

ANSWER: Mankind denies the allegations in this paragraph.

60. Mankind's infringement of the '524 Patent and inducement of such infringement is and will be knowing and willful.

ANSWER: Mankind denies the allegations in this paragraph.

COUNT II
INFRINGEMENT OF THE '587 PATENT

61. Par incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Mankind incorporates each of the preceding answers as if fully set forth herein.

62. Mankind's manufacture, importation, and commercial sale of the Accused Tablets constitutes infringement of the '587 patent under at least 35 U.S.C. § 271(a) and (b), including without limitation claim 1 thereof.

ANSWER: Mankind denies the allegations in this paragraph.

63. In particular, the Accused Tablets include varenicline tartrate as the active ingredient and have levels of nitrosamines and other impurities that fall within the limitations of the '587 Patent, including without limitation at least claim 1 thereof.

ANSWER: Mankind admits that the products that are the subject of ANDA No. 214255 include varenicline tartrate as the active ingredient. Mankind admits that the products that are the subject of ANDA No. 214255 have levels of nitrosamine impurities that are below 50 parts per

million. Mankind denies that the products that are the subject of ANDA No. 214255 infringe claim 1 of the '587 patent, or any other claim of any asserted patent. Mankind denies the remaining allegations in this paragraph.

64. Upon information and belief, Mankind is manufacturing the Accused Tablets in India and importing them in the United States for commercial sale throughout the country.

ANSWER: Mankind admits that Mankind manufactures the products that are the subject of ANDA No. 214255 in India. Mankind further admits that the products that are the subject of ANDA No. 214255 are imported into the United States for commercial sale. Mankind denies the remaining allegations in this paragraph.

65. Mankind has continued and is continuing to make, import, and sell the Accused Products following issuance of the '587 patent, thereby infringing the '587 patent under at least 35 U.S.C. § 271(a) and (b).

ANSWER: Mankind admits that Mankind manufactures the products that are the subject of ANDA No. 214255 in India. Mankind further admits that the products that are the subject of ANDA No. 214255 are imported into the United States for commercial sale. Mankind denies the remaining allegations in this paragraph.

66. To the extent Mankind has not and will not itself import, use, sell, or offer to sell the Accused Products in the United States, it has and will knowingly, intentionally, and actively induce and encourage others to do so, with full knowledge of the '587 patent, and thereby infringe the '587 patent under 35 U.S.C. § 271(b).

ANSWER: Mankind denies the allegations in this paragraph.

67. Mankind's infringement, if unchecked, will cause Par to suffer significant, immediate, and irreparable damage.

ANSWER: Mankind denies the allegations in this paragraph.

68. Mankind's infringement of the '587 patent and inducement of such infringement is and will be knowing and willful.

ANSWER: Mankind denies the allegations in this paragraph.

PRAYER FOR RELIEF

Mankind specifically denies that Plaintiffs are entitled to the general or specific relief requested against Mankind, or to any relief whatsoever, and prays for judgment in favor of Mankind dismissing this action with prejudice, and awarding Mankind its reasonable attorney fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Mankind hereby asserts the following defenses without undertaking or otherwise shifting any applicable burdens of proof. Mankind reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

First Affirmative Defense

The claims of the '524 patent are invalid and/or unenforceable under one or more provisions of 35 U.S.C. § 100 et seq., such as sections 101, 102, 103, and/or 112, or other judicially created bases for invalidation, such as double patenting.

Second Affirmative Defense

The claims of the '587 patent are invalid and/or unenforceable under one or more provisions of 35 U.S.C. § 100 et seq., such as sections 101, 102, 103, and/or 112, or other judicially created bases for invalidation, such as double patenting.

Third Affirmative Defense

The filing of ANDA No. 214255 has not infringed, and does not infringe, any valid and enforceable claims of the '524 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

Fourth Affirmative Defense

The manufacture, use, sale, offer for sale, or importation of the products that are the subject of ANDA No. 214255 has not infringed, does not infringe, and would not infringe, any valid and enforceable claim of the '524 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

Fifth Affirmative Defense

The filing of ANDA No. 214255 has not infringed, and does not infringe, any valid and enforceable claims of the '587 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

Sixth Affirmative Defense

The manufacture, use, sale, offer for sale, or importation of the products that are the subject of ANDA No. 214255 has not infringed, does not infringe, and would not infringe, any valid and enforceable claim of the '587 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

Seventh Affirmative Defense

Par is estopped from arguing that the claims of the '524 patent encompass any process other than the claimed acid-base treatment disclosed in the '524 patent specification under prosecution history estoppel and/or disclaimer.

Eighth Affirmative Defense

Par is estopped from arguing that the claims of the '587 patent encompass any product other than the product made by the process disclosed in the '587 patent specification under prosecution history estoppel and/or disclaimer.

Ninth Affirmative Defense

Plaintiffs' complaint fails to state a claim upon which relief can be granted.

Tenth Affirmative Defense

Mankind's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Eleventh Affirmative Defense

Any additional defenses or counterclaims that discovery may reveal.

WHEREFORE, Mankind requests that Plaintiffs' First Amended Complaint be dismissed with prejudice and that Mankind be awarded the costs of this action, its attorney fees, and all other relief that this Court deems just and proper.

Dated: December 26, 2023

Respectfully submitted,

/s/ Rex Mann

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing document has been on counsel of record who are deemed to have consented to electronic service on December 26, 2023, via electronic filing using the Court's CM/ECF system.

/s/ Rex Mann
Rex Mann